510(k) Summary - ABL800 FLEX with FLEXQ Module

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Date Summary Prepared: November 19, 2004

Device Trade Name: ABL800 FLEX with FLEXQ Module
Common name: Blood Gas, Co-oximetry, Electrolyte and Metabolite Analyzer
Classification Name: Blood gases and blood pH test system (21 CFR Section 862.1120)

Predicate Devices

RADIOMETER ABL800 FLEX (K041874) and AVL 9181 Electrolyte Analyzer (K972673).

Device Description

The ABL800 FLEX with FLEXQ Module is an ABL800 FLEX Analyzer with the added optional capability of automatic sampling from of up to three blood samplers. Thus, the analyzer part of the ABL800 FLEX with FLEXQ is identical to the analyzer part of the ABL800 FLEX. As with the ABL800 FLEX, the ABL800 FLEX with FLEXQ Module consists of several models of the same analyzer for the measurement of blood gas, electrolyte, metabolite and co-oximetry. The FLEXQ module is designed to work with the vented arterial blood sampler, *safe*PICO (subject of a separate 510(k) application).

In the sampler barrel the *safe*PICO includes a magnetic steel ball that may be activated by the FLEXQ module for automatically mixing the sample before measurement. On the outside of the barrel, each *safe*PICO sampler has a unique barcode that may be read by the FLEXQ module. The *safe*PICO sampler is delivered with a new vented tip cap that allows the sampler to be vented after the appliance of the tip cap to the sampler. The sample is introduced into the analyzer by the inlet probe of the ABL800 FLEX Analyzer penetrating the top of the tip cap and entering the sampler.

Installing a FLEXQ module into an existing ABL800 FLEX Analyzer includes physically installing the module and loading upgraded software, which controls the function of the FLEXQ module. The FLEXQ module comprises a sampler tray with three slots for holding up to three samplers simultaneously. Each slot has an optical switch detecting the presence of a sampler. The FLEXQ module has a barcode reader, which can read out the barcode of the samplers. Further, the FLEXQ module includes a rotating magnet system located under the sampler tray, which interacts with the steel ball in the sampler barrel and thus automatically mixes the sample prior to measuring.

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Example of automatic queuing and analyzing a sample:
When a blood sample has been performed as prescribed with the *safe*PICO sampler, the sampler is provided with the vented tip cap on the syringe luer tip and arranged in a free slot of the FLEXQ sampler tray. The presence of the sampler is detected and the barcode of the sampler is read out. The sampler is now put in queue to be analyzed. When the analyzer is ready to analyze the blood sample, the magnet system is activated to rotate and move the steel ball in the sampler in approximately 5 seconds to mix the sample. The sampler tray is then displaced to position the sampler in front of the inlet of the analyzer. The inlet probe of the analyzer penetrates the top of the tip cap and enters the sample barrel to aspirate the blood sample into the analyzer. The sample is then analyzed and the sampler may be removed and discarded as prescribed.

The upgraded software controls all steps of the FLEXQ module and the ABL800 FLEX Analyzer. If required, manual introduction of a blood sample may be performed as well. This may be relevant when having only small sample volumes e.g. in capillary tubes, or if it becomes necessary to perform an urgent measurement when all three slots of the FLEXQ sample tray are occupied.

Intended Use

The ABL800 FLEX with FLEXQ Module is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, FCOHb, FMetHb, FHHb and FHbF) as well as for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2.

Statement of Indication for Use

Indication for use information for the analytes measured by the ABL800 FLEX with FLEXQ Module:

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.

pO_2: The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

pCO_2: pCO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.

Potassium (cK^+): The measurements of the concentration of potassium ions in plasma are used to monitor the electrolyte balance.

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Sodium (*c*Na^+): The measurements of the concentration of sodium ions in plasma are used to monitor the electrolyte balance.

Calcium (*c*Ca^{2+}): The measurements of the concentration of calcium ions in plasma are used to monitor the electrolyte balance.

Chloride (*c*Cl^-): The measurements of the concentration of chloride ions in plasma are used to monitor the electrolyte balance.

Glucose (*c*Glu): The glucose measurements measure the concentration of glucose in plasma. The glucose measurements are used to screen for, diagnose and monitor diabetes, pre-diabetes, and hyper- and hypoglycemia.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements serve as a marker of critical imbalance between tissue oxygen demand and oxygen supply.

Bilirubin (*c*tBil): The bilirubin measurements measure the total concentration of bilirubin in plasma. *c*tBil is used to assess the risk of hyperbilirubinemia.

Total Hemoglobin (*c*tHb): *c*tHb is a measure of the potential oxygen-carrying capacity of the blood.

Oxygen Saturation (sO_2): *s*O2 is the percentage of oxygenated hemoglobin in relation to the amount of hemoglobin capable of carrying oxygen. *s*O2 allows evaluation of oxygenation.

Fraction of Oxyhemoglobin (FO_2Hb): FO_2Hb is a measure of the utilization of the potential oxygen transport capacity; that is the fraction of oxyhemoglobin in relation to all hemoglobins present (tHb) including dyshemoglobins.

Fraction of Carboxyhemoglobin (*F*COHb): *F*COHb is the fraction of carboxyhemoglobin. It is incapable of transporting oxygen.

Fraction of Methemoglobin (*F*MetHb): *F*MetHb is the fraction of methemoglobin. It is incapable of transporting oxygen.

Fraction of Deoxyhemoglobin in Total Hemoglobin (*F*HHb): *F*HHb is the fraction of deoxyhemoglobin in total hemoglobin. It can bind oxygen then forming oxyhemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): Fetal hemoglobin consists of two α-chains and two β-chains, and has a higher oxygen affinity than adult Hb.

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Clinical Interpretation

Clinical interpretation for the analytes measured by the ABL800 FLEX with FLEXQ Module:

pH: Common causes of low pH (acidosis) may be A) respiratory acidosis as alveolar hypoventilation or increased metabolic rate or B) metabolic acidosis as circulatory impairment, renal failure, diabetic ketoacidosis or gastro-intestinal loss of bicarbonate (diarrhea). Common causes of high pH (alkalosis) may be A) respiratory alkalosis as alveolar hyperventilation or B) metabolic alkalosis as diuretics, gastrointestinal loss of acid (vomiting) or hypokalemia (low cK^+).

pO_2: Common causes of low pO_2 is pulmonary disease, cardiac right to left shunt, low alveolar ventilation and ambient pressure.

pCO_2: Common causes of low pCO_2 (alveolar hyperventilation - hypocapnia) may be A) aggressive ventilator treatment or psychogenic hyperventilation or B) compensatory to metabolic acidosis, secondary to central nervous system affection or secondary to hypoxia. Common causes of high pCO_2 (alveolar hypoventilation - hypercapnia) may be lung disease, central nervous system depression, either primary, or secondary to sedation or analgesics or ventilator treatment, either with strategy of permissive hypercapnia or with too low alveolar ventilation.

Potassium (cK^+): Common causes of low cK^+ may be diuretics, diarrhoea, vomiting, respiratory or metabolic baseosis or hyperaldosteronism. Common causes of high cK^+ may be renal failure, metabolic acidosis or toxic acidosis (salicylate, methanol, etc.).

Sodium (cNa^+): Common causes of low values of cNa^+ may be water intoxication, renal failure, heart failure, liver failure, increased ADH secretion, diuretics or nephrotic syndrome. Common causes of high values of cNa^+ may be increased Na-load, steroids, vomiting, diarrhea, excessive sweating or osmotic diuresis.

Calcium (cCa^{2+}): Common causes of low values of cCa^{2+} may be baseosis, renal failure, acute circulatory insufficiency, lack of vitamin D or hypoparathyroidism. Common causes of high values of cCa^{2+} may be malignancies, thyreotoxicosis, pancreatitis, immobilization or hyperparathyroidism.

Chloride (cCl^-): Common causes of low cCl^- may be primary metabolic acidosis or a secondary metabolic acidotic compensation for respiratory alkalosis. Common causes of high cCl^- may be metabolic alkalosis either as primary disorder of as compensation for chronic respiratory acidosis.

Glucose (cGlu): Common causes of low cGlu may be insulin overdose, adrenal insufficiency and extensive liver disease. Common causes of high cGlu may be lack of insulin, acute stress (response to trauma, heart attack, and stroke).

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Lactate (*c*Lac): In most situations, elevated blood lactate will be caused by hypoperfusion, severely impaired arterial oxygen supply, or a combination of the two. Decreasing or persistently low levels of blood lactate (*c*Lac) during critical illness signal successful treatment.

Bilirubin (*ct*Bil): Bilirubin is formed as a result of the catabolism of hemoglobin. Typically, the major part of bilirubin in plasma comes from the breakdown of red cells. Neonates have an increased breakdown of hemoglobin, limited hepatic function and low concentrations of albumin. If the concentration of bilirubin in neonates exceeds defined levels it requires specific therapy.

Total Hemoglobin (*ct*Hb): High values of *c*tHb typically indicate a high blood viscosity, which increases the afterload to the heart and thereby can cause forward failure. In extreme cases, the microcirculation can be impaired. Common causes of high values of *c*tHb (polycytemia) may be A) polycytemia vera or B) dehydration, chronic lung disease, chronic heart disease, living at high altitude or trained athletes. Low concentrations of total hemoglobin or effective hemoglobin imply a risk of tissue hypoxia because of the lowered arterial oxygen content (*c*tO2). Common causes of low values *c*tHb (anemia) may be A) impaired red cell production or B) hemolysis, bleeding, dilution (overhydration) or multiple blood samples (neonates).

Oxygen Saturation (sO_2): High (normal) sO_2 may be a measure of sufficient utilization of actual oxygen transport capacity. Common causes of low sO_2 may be impaired oxygen uptake.

Fraction of Oxyhemoglobin (FO_2Hb): High (normal) *F*O2Hb may be an indication of sufficient utilization of oxygen transport capacity. Common causes of low FO_2Hb may be impaired oxygen uptake or presence of dyshemoglobins.

Fraction of Carboxyhemoglobin (*F*COHb): *F*COHb levels are normally below 2 %, but heavy smokers may have up to 9-10 %. Newborns may present up to 10-12 % of *F*COHb because of an increased hemoglobin turnover combined with a less developed respiratory system. In the acute exposition, headache, nausea, dizziness and chest pain occur with 10-30 %. Severe headache, general weakness, vomiting, dyspnea and tachycardia occur at 30-50 %. Above 50 %, seizures, coma and death occur.

Fraction of Methemoglobin (*F*MetHb): *F*MetHb levels above 10-15 % can result in pseudocyanosis. Methemoglobinemia may cause headache and dyspnea at levels above 30 % and may be fatal, especially in levels above 70 %.

Fraction of Deoxyhemoglobin in Total Hemoglobin (*F*HHb): *F*HHb is an expression of the amount of hemoglobin not bound to oxygen, but capable of being bound to oxygen if the oxygen supply is increased.

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Fraction of Fetal Hemoglobin (*F*HbF): *F*HbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

Performance Test

Comparison tests verifying that the ABL800 FLEX with FLEXQ Module performs equivalent to the predicate devide ABL800 FLEX (K041874) will be performed.

Summary of Technological Characteristics

The measuring technology of the ABL800 FLEX with FLEXQ Module includes electrochemical and optical technology. The sensors for measuring blood gases and pH, sodium, potassium, calcium, chloride, glucose and lactate are electrochemical sensors. The electrochemical sensors are based on potentiometric and amperometric methods.

The optical system of the ABL800 FLEX with FLEXQ Module for measuring co-oximetry parameters and bilirubin includes a 128-wavelength spectrophotometer. The system is based on absorbance measurements.

The FLEXQ module automates the inlet of sample including reading of sample ID and mixing of the sample. The module has a sampler tray with three sampler slots, a barcode reader and a sample mixing system comprising a rotating magnet system.

The ABL800 FLEX with FLEXQ Module may be interfaced with the RADIANCE STAT analyzer management system software as well as with the hospital LIS/HIS systems through network interfaces.

The ABL800 FLEX with FLEXQ Module is similar in technological characteristics, device performance and intended use as the predicate devices and is therefore substantially equivalent to the predicate devices.

Conclusion

The ABL800 FLEX with FLEXQ Module is substantially equivalent in features and characteristics to the predicate devices, ABL800 FLEX (K041874) and AVL 9181 Electrolyte Analyzer (K972673).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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MAY 1 0 2005

Ms. Lene Meineche Marnæs
Regulatory Affairs
Radiometer Medical Aps
Akandevej 21
Brønshøj
Denmark DK-2700

Re: k043218
Trade/Device Name: ABL800 FLEX with FLEXQ Module
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pCO_2, pO_2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, KHP, CIG, MQM, GHS, GKR, KQI
Dated: March 11, 2005
Received: March 16, 2005

Dear Ms. Marnæs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K043218

Device Name: ABL800 FLEX with FLEXQ Module

Intended Use:
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Indication for use information for the analytes measured by the ABL800 FLEX:

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***p*O_2:** The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Device Evaluation and Safety

510(k) K043218

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